targeting molecule comprise a J chain or portion thereof that specifically binds to a basolateral factor. Also required is that the targeting molecule not comprise a full-length immunoglobulin, and that the biological agent not be native to the targeting molecule and not be iodine.

The new claims find ample basis in the specification and claims as originally filed. For example, support for "J chain or portion thereof that specifically binds to a basolateral factor" is found, for example, at page 8, lines 29-30 and page 9, lines 11-14. Support for the biological agent to not be native to the targeting molecule and to not include iodine is found at page 30, lines 5-7. Support for a targeting molecule that comprises the various recited portions of a full length immunoglobulin (but not full length immunoglobulin) is found, for example, at page 9, lines 17-22 (portions of IgA or IgM) and page 14, line 29 to page 15, line 2 (portions of Ig-derived sequences). Accordingly, the new claims raise no issue of new matter.

REJECTION UNDER 35 U.S.C. § 112

The rejection of claims 1-31 and 36-41 under 35 U.S.C. 112 (first and second paragraph) is rendered moot by cancellation of the claims. It is respectfully submitted that the new claims are fully enabled and definite within the meaning of patent statute.

REJECTION UNDER 35 U.S.C. § 102 OVER FERKOL

The rejection of claims 1, 2, 6-18 and 31 under 35 U.S.C. § 102(b) as being allegedly anticipated by Ferkol et al., which was traversed in the Amendment mailed June 8, 2000, is rendered moot by cancellation of the claims. It is respectfully submitted that the new claims are not anticipated by this reference. Ferkol et al., describes the use of Fab fragments of an IgG class anti-pIgR antibody to deliver DNA into human colon carcinoma cells. Such antibody does not include a J chain or portion thereof. Accordingly, Ferkol cannot anticipate the new claims.

REJECTION UNDER 35 U.S.C. § 102 OVER LEMAITRE-COELHO ET AL.

The rejection of claims 1, 2, 6-18 and 31 under 35 U.S.C. § 102(b) as being allegedly anticipated by Lemaitre-Coelho et al., which was traversed in the Amendment

mailed June 8, 2000, is rendered moot by cancellation of the claims. It is respectfully submitted that the new claims are not anticipated by the reference. Lemaitre-Coelho et al., labels a polymeric human IgA and IgA Fc fragment with iodine, injects them i.v. into rats and observes accumulation of iodine in the bile duct. The reference, however, does not describe a biological agent that is not native to the targeting molecule and is not iodine. Accordingly, Ferkol cannot anticipate the new claims.

REJECTION UNDER 35 U.S.C. § 103(a)

The rejection of claims 1-31 and 36-41 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Terskikh et al., and Ferkol et al. in view of Morton et al., Carayannopoulus et al. (both the PNAS and JEM reference), and further in view of Weissleder et al., Janoff et al., Shen et al., Weiner et al. and the Pierce Chemical Company catalogue, which was traversed in the Amendment mailed June 8, 2000, is rendered moot by cancellation of the claims. It is respectfully submitted that the new claims are not rendered obvious by the reference.

Terskikh does not teach a targeting molecule that does not comprise a full-length immunoglobulin. Furthermore, Terskikh does not teach a biological agent is not native to the targeting molecule and is not iodine. Ferkol, as already discussed, fails to teach a J chain or a variant thereof linked to a biological agent.

Morton and the two Carayannopoulus references describe the preparation of monomeric IgA by recombinant expression. These authors of these references are seeking to gain an increased understanding of how the IgA α chain is bound by the Fcα receptor on monocytes. These references, therefore, do not teach a targeting molecule that is J chain or a portion thereof linked to at least one biological agent. These references moreover do not teach a biological agent that is not native to the targeting molecule and is not iodine. Thus, Morton and the two Carayannopoulus references cannot cure the cited deficiencies in the main references, Terskikh and Ferkol.

The stated motivation to combine these references is an alleged desire to delete or mutate the Fc receptor binding site on IgA to achieve greater specificity of the targeting molecule. First, It is pointed out that the examiner has failed to make a prima facie rejection as no basis was given to support this alleged motivation. In addition, Applicants

respectfully submit that the alleged motivation cannot be supported in any event because it is improperly based on hindsight reasoning; It assumes that the art appreciated the use of a targeting molecule linked to at least one biological agent, wherein the targeting molecule comprises a J chain or portion thereof that specifically binds to a basolateral factor and where the biological agent is not native to the targeting molecule and is not iodine. Applicants, however, were the first to make this discovery.

Furthermore, the examiner's reliance on recombinant expression to support the alleged motivation is misplaced because those in the art who were expressing IgA by recombinant means were motivated to make fragments of the IgA α chain to study monocyte Fc receptor binding, not targeting of an epithelial basolateral factor via a J chain linked to a biological agent. Indeed, the role of J chain in translocating IgA and IgM through an epithelial layer has been known for more than thirty years (see, e.g., Brandtzaeg, Clin Exp Immunol 1981 May;44(2):221-32, "Transport models for secretory IgA and secretory IgM") but this did not, prior to Applicants invention, motivate the recombinant IgA art to desire, let alone teach the claimed invention.

It is further noted that the teachings of Weissleder, Janoff, Shen, Weiner and the Pierce chemical company catalog, alleged by the examiner to teach covalent linkage of gentamicin to a targeting molecule, taken alone or in combination also fail to cure the deficiencies in Terskikh and Ferkol in view of Morton and the two Carayannopoulus references. Accordingly, the new claims are not obvious over Terskikh et al., and Ferkol et al. in view of Morton et al., Carayannopoulus et al. (both the PNAS and JEM reference), and further in view of Weissleder et al., Janoff et al., Shen et al., Weiner et al. and the Pierce Chemical Company catalogue.

REJECTION FOR DOUBLE PATENTING

The prior rejections of claims 1-31 and 36-41 for statutory double patenting and for provisional obviousness type double patenting, which was traversed in the Amendment mailed June 8, 2000, is rendered moot by cancellation of the claims. It is respectfully submitted that the new claims are not subject to double patenting for many of the same reasons set forth in the cited Amendment.

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Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is urged to contact the undersigned by telephone to address any outstanding issues standing in the way of an allowance.

Respectfully submitted,

Date: February 28, 2002

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